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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---------------------------------------|-------------|----------------------|---------------------|------------------|
| 10/042,431 | 10/25/2001 | Sean A. McCarthy | 10147-6U2 | 5729 |
| 570 | 7590 | 11/28/2003 | EXAMINER | |
| AKIN GUMP STRAUSS HAUER & FELD L.L.P. | | | NASHED, NASHAAT T | |
| ONE COMMERCE SQUARE | | | ART UNIT | |
| 2005 MARKET STREET, SUITE 2200 | | | PAPER NUMBER | |
| PHILADELPHIA, PA 19103-7013 | | | 1652 | |

DATE MAILED: 11/28/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|--|--------------------------------------|--|--|
| <p align="center">Office Action Summary</p> | Application No. 10/042,431 | Applicant(s) MCCARTHY ET AL. | |
| | Examiner Nashaat T. Nashed | Art Unit 1652 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 25 October 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) _____ is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-51 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
 a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

Claims 1-51 are pending.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- | | |
|--------------|--|
| Groups 1-6 | Claims 1-7, and 12, drawn to nucleic acid, vector host cell and a recombinant method to make the polypeptide of SEQ ID NO's: 47-52, respectively, classified in Class 536, subclasses 23.2, and classified in Class 435, subclasses 183. Select one sequence for prosecution. |
| Groups 7-12 | Claims 8-10, drawn to a polypeptide of SEQ ID NO: 47-52, respectively, classified in Class 435, subclass 183. Select one sequence for prosecution. |
| Groups 13-18 | Claims 11, 13-15, and 23, drawn to antibody raised against the polypeptide of SEQ ID NO's: 47-52, respectively, and method of use, classified in Class 530, subclass 387.1. Select one sequence for prosecution. |
| Groups 19-24 | Claims 16-18 and 37-42, drawn to a hybridization probes and method of detecting nucleic acid encoding the polypeptide of SEQ ID NO: 47-52, respectively, classified in Class 435, subclass 6. Select one sequence for prosecution. Select one sequence for prosecution. |
| Groups 25-30 | Claim 19, 20 and 22 (claims 28-30 are also included in Group 25 only), drawn to a method of identifying a compound that binds to the polypeptide of SEQ ID NO's: 47-52, respectively, classified in Class 435, subclass 18. Select one sequence for prosecution. |
| Groups 31-36 | Claims 21 (claims 31,32, 34-45, 47, 48, 50, and 51 are included in Group 31), drawn to a method of modulating the activity of the polypeptide of SEQ ID NO: 47-52, respectively, classification of this Group is unknown because the specification has not exemplified the structure of modulator of the polypeptide. Select one sequence for prosecution. |
| Group 37 | Claims 33, 46, and 49, drawn to a method of making pharmaceutical composition for TANGO 294-like lipase, classification of this Group is unknown because the specification has not exemplified the structure of modulator of the polypeptide of SEQ ID NO: 47. |

The inventions are distinct, each from the other because of the following reasons:

The nucleic acids of Groups 1-6 are independent chemical entities and require different searches in the patent and non-patent literature.

The polypeptides of Groups 7-12 are independent chemical entities and require different searches in the patent and non-patent literature.

The antibodies of Group 13-18 are independent chemical entities and require different searches in the patent and non-patent literature.

The hybridization probes of Group 19-24 are independent chemical entities and require different searches in the patent and non-patent literature.

The nucleic acids of Groups 1-6, the polypeptides of Groups 7-12, the antibodies of Groups 13-18, and the hybridization probes of Groups 19-24 are independent chemical entities and require different searches in the patent and non-patent literature. Claims drawn to method of making proteins using the recombinant DNA would be placed with the DNA of Group I because, although they have acquired a separate status in the art as shown by their different classification, they do not constitute a burden to search them in addition to the DNA sequences.

Inventions of Groups 1-6 and those of Groups 25-37 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions are not disclosed as capable of use together because the methods of Groups 25-37 do not utilize the nucleic acids of Groups 1-6.

Each of the polypeptides of Groups 7-12 and those of Groups 25-30 and 31-36, respectively, are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the polypeptides of Groups 7-12 can be utilized in other methods such as making antibodies.

With the exception of one of the polypeptide, the polypeptides of Groups 7-12 and those of Groups 25-36, respectively, are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, each of the methods of Groups 25-36 utilizes only one polypeptide

corresponding to the polypeptides of Groups 7-12, respectively, and does not utilize any of the others.

Inventions of Groups 13-18 and those 25-37 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the methods of Groups 25-37 do not utilize any of the antibodies of Groups 13-18.

Inventions of Groups 19-24 and those 25-37 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the methods of Groups 25-37 do not utilize any of the hybridization probes of Groups 19-24.

Inventions of Groups 25-37 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions are independent methods having different steps and use different reagents.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35

U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**


Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nashaat T. Nashed, Ph. D. whose telephone number is (703) 305-6586. The examiner can normally be reached Monday, Tuesday, Thursday and Friday from 9:00 a.m. to 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached on (703) 308-3804. The fax phone numbers for this Group are (703) 305-3014 and (703)308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.


Nashaat T. Nashed, Ph. D.
Primary Examiner